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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA WOMEN'S HEALTH, INC., Plaintiff, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	DOCUMENT FILED ELECTRONICALLY C.A. No. 3:09-cv-05112-MLC-TJB

ANSWER AND COUNTERCLAIM OF
LUPIN PHARMACEUTICALS, INC. AND LUPIN, LTD.

Defendants and Counter-Plaintiffs Lupin Pharmaceuticals, Inc., ("LPI") having its principal place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202, and Lupin Limited ("Lupin Ltd."), having its principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India (collectively "Lupin"), by and through their attorneys, respond to each of the numbered paragraphs to the Complaint filed against it by Plaintiff and Counter-Defendant Teva Women's Health, Inc. ("Teva") as follows:

NATURE OF THE ACTION

1. Lupin admits that this action for alleged infringement of U.S. Patent No. Re. 39,861 ("the '861 patent") purports to arise under the patent laws of the United States.

THE PARTIES

2. Lupin is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2 of the Complaint and, therefore denies them.

3. Lupin admits that LPI. is a corporation organized under the laws of the Commonwealth of Virginia, with a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Lupin admits that LPI is a wholly owned subsidiary of Lupin Ltd. and that LPI distributes pharmaceutical products for sale and use in the State of New Jersey. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over LPI, but denies the remaining allegations in paragraph 3 of the Complaint.

4. Lupin admits that Lupin Ltd. is a corporation organized under the laws of India, with a principal place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India. Lupin admits that Lupin Ltd. develops and manufactures generic pharmaceutical products for sale and use throughout the United States and in this District. Lupin admits that LPI distributes generic pharmaceutical products for sale and use throughout the United States and in this District. For the purposes of this action only, Lupin does not contest that this Court

has personal jurisdiction over Lupin Ltd., but denies the remaining allegations in paragraph 4 of the Complaint.

JURISDICTION AND VENUE

5. Lupin admits that subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) is proper for the claims directed against Lupin Ltd. only. Lupin denies that subject matter jurisdiction exists over the claim of infringement based on 35 U.S.C. §271(e) insofar as it is directed to LPI. To the extent there are any remaining allegations in paragraph 1 of the Complaint, Lupin denies them.

6. Lupin admits that Lupin Ltd. develops and manufactures generic pharmaceutical products for sale and use throughout the United States and in the State of New Jersey. Lupin admits that LPI distributes generic pharmaceutical products for sale and use throughout the United States and in the State of New Jersey. For the purposes of this action only, Lupin does not contest that this Court has personal jurisdiction over Lupin Ltd. and LPI, but denies the remaining allegations in paragraph 6 of the Complaint..

7. Lupin does not contest that venue is proper as to it in this Court, but denies the remaining allegations in paragraph 7 of the Complaint.

BACKGROUND

8. On information and belief, Lupin admits that on September 25, 2007 the United States Patent and Trademark Office ("PTO") issued the '861 patent, entitled "Methods of Extended Use Oral Contraception," to Duramed Pharmaceuticals, Inc.,

now known as Teva Women's Health, Inc.. Lupin admits that the '861 patent lists Gary D. Hodgen as the inventor, that the '861 patent is currently set to expire on June 23, 2017 and that a copy of the '861 patent is attached to the Complaint as Exhibit A. Lupin denies that the '861 patent was "legally" issued by the PTO or that the '861 patent is valid and enforceable. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 8 of the Complaint and, therefore denies them.

9. Lupin admits that the '861 patent is directed to a method of extended female contraception that reduces the number of menstrual periods per year, which comprises orally monophasicly administering to a pre-menopausal female, a combination of estrogen and progestin for 84 consecutive days in which the daily amounts of estrogen and progestin are equivalent to about 30 mcg of ethinyl estradiol and about 0.25 to 1.5 mg of norethindrone acetate, respectively, followed by administration of a placebo for a period of 5 to 8 days, wherein the combination of estrogen and progestin and the placebo are packaged together in a kit and wherein the method of female contraception reduces the number of menstrual periods per year to four when the method is practiced for at least one year. To the extent there are any remaining allegations in paragraph 9 of the Complaint, Lupin denies them.

10. Lupin admits that the United States Food and Drug Administration ("FDA") approved New Drug Application No. 21-544 allowing the NDA holder to sell an oral contraceptive product under the trade name Seasonale®. Lupin admits that Seasonale® comprises 84 active tablets containing a combination of 30 mcg ethinyl estradiol and 0.15 mg levonorgestrel. On information and belief, Lupin admits that

Seasonale® allows women to reduce the number of menstrual periods to 4 per year when Seasonale® is administered for a full year. To the extent there are any remaining allegations in paragraph 10 of the Complaint, Lupin denies them.

11. Lupin admits the allegations in paragraph 11 of the Complaint.

12. On information and belief, Lupin admits that Teva sells one or more drug products under the trade name Seasonale® in the United States pursuant to NDA No. 21-544. Lupin is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 12 of the Complaint and, therefore denies them.

ACTS GIVING RISE TO THIS ACTION

13. Lupin admits that Lupin Ltd. notified Duramed Pharmaceuticals, Inc., Barr Laboratories, Inc., Teva Pharmaceuticals, USA and Teva Corporate Headquarters by letter dated August 24, 2009 that Lupin Ltd. had submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 91-440 seeking approval to manufacture, sell and distribute a product comprising 84 active tablets containing 0.15 mg levonorgestrel and 30 mcg ethinyl estradiol with 7 placebo tablets ("the Lupin Product") prior to the expiration of the '861 patent. To the extent there are any remaining allegations in paragraph 13 of the Complaint, Lupin denies them.

14. Lupin admits that the purpose of Lupin Ltd.'s filing of ANDA No. 91-440 is to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use and sale of the Lupin Product prior to the expiration of the '861 patent. To the extent there are any remaining allegations in paragraph 14 of the Complaint, Lupin denies them.

15. Lupin admits that Lupin Ltd. submitted its ANDA No. 91-440 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that the claims of the '861 patent are invalid and/or will not be infringed by the manufacture, use or sale of the Lupin product. Lupin denies the remaining allegations of paragraph 15 of the Complaint.

16. Lupin admits that in Lupin Ltd.'s notice letter, Lupin Ltd. indicates that it filed ANDA No. 91-440 seeking FDA approval to commercially sell and market the Lupin Product throughout the United States (including the State of New Jersey) prior to the expiration of the '861 patent. Lupin denies the remaining allegations in paragraph 16 of the Complaint.

17. Lupin admits the allegations in paragraph 17 of the Complaint.

18. Lupin admits the allegations in paragraph 18 of the Complaint.

19. Lupin admits the allegations in paragraph 19 of the Complaint.

COUNT I: PATENT INFRINGEMENT
(U.S. Patent No. Re. 39,861)

20. Lupin incorporates by reference its answers to paragraphs 1 to 18 of the Complaint as if restated fully herein.

21. Lupin denies the allegations in paragraph 21 of the Complaint.

22. Lupin denies the allegations in paragraph 22 of the Complaint.

23. Lupin denies the allegations in paragraph 23 of the Complaint.

24. Lupin denies the allegations in paragraph 24 of the Complaint.

25. Lupin denies the allegations in paragraph 25 of the Complaint.

26. Lupin denies the allegations in paragraph 26 of the Complaint.

27. Lupin denies the allegations in paragraph 27 of the Complaint.

DEFENSES

Further responding to the Complaint, and as additional defenses thereto, Lupin asserts the following defenses, without admitting any allegations of the Complaint not otherwise admitted and without assuming any burden when such burden would otherwise be on Teva.

FIRST DEFENSE
(Invalidity of the '861 Patent)

28. All of the claims of the '861 patent are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. § 101 *et seq*. By way of example and not of limitation, the claims of the '861 patent are invalid under 35 U.S.C. §§ 102 or 103.

SECOND DEFENSE
(Failure to State a Claim)

29. To the extent that Teva alleges that submission of ANDA No. 91-440 makes this case exceptional under 35 U.S.C. §285, the Complaint fails to state a claim upon which relief can be granted and must be dismissed.

THIRD DEFENSE
(Improper Party)

30. LPI is not a proper party to this action.

COUNTERCLAIMS

Further responding to the Complaint, Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively "Lupin") allege the following counterclaims, without admitting any allegations of the Complaint not otherwise admitted and without assuming the burden when such burden would otherwise be on Teva Women's Health, Inc. ("Teva").

THE PARTIES

1. Lupin Limited ("Lupin Ltd.") is an Indian corporation having a place of business at Laxmi Towers, B Wing, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

2. Lupin Pharmaceuticals, Inc. ("LPI") is a Virginia corporation having a place of business at Harborplace Tower, 111 S. Calvert Street, 21st Floor, Baltimore, Maryland 21202.

3. Upon information and belief, Teva Women's Health, Inc. is a corporation organized and existing under the laws of the State of Delaware, having an established place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§1331 and 1338(a), and pursuant to 35 U.S.C. §271(e)(5), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. §1 *et seq.*

5. This Court has personal jurisdiction over Teva by virtue of the fact that Teva conducts business in the State of New Jersey, has availed itself of the rights and

benefits of New Jersey law, and has engaged in substantial and continuing contacts with New Jersey.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

THE CONTROVERSY

7. Lupin holds Abbreviated New Drug Application ("ANDA") No. 91-440 for a product comprising 84 tablets containing 0.15 mg levonorgestrel and 30 mcg ethinyl estradiol with 7 placebo tablets.

8. On or about October 6, 2009, Teva filed the present action against Lupin alleging infringement of U.S. Patent No. Re. 39,861 ("the '861 patent") arising from Lupin's submission of ANDA No. 91-440. There is a substantial controversy between the parties by reason of the commencement by Teva of this action and the filing by Lupin Ltd. of ANDA 91-440 with a certification that the '861 patent is invalid and/or will not be infringed by the manufacture, sale and use of Lupin's product covered by ANDA 91-440 ("ANDA product"). Lupin and Teva have adverse legal interests with respect to the '861 patent of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. The '861 patent effectively prevents approval of Lupin Ltd.'s ANDA product by the United States Food and Drug Administration.

COUNT I

(Declaratory Judgment of Invalidity of the '861 Patent)

9. Lupin repeats and incorporates by reference paragraphs 1 to 8 of its Counterclaims.

10. The claims of the '861 patent are invalid for failing to meet a condition for patentability set forth in 35 U.S.C. §101 *et seq*. By way of example and not of limitation, the claims of the '861 patent are invalid under 35 U.S.C. §§ 102 or 103.

PRAYER FOR RELIEF

WHEREFORE, Lupin respectfully requests the Court enter judgment against Plaintiff and Counter-Defendant Teva to include:

(a) a declaration that Lupin's commercial manufacture, use, offer for sale, sale, or importation of its ANDA product will not infringe any valid claim of the '861 patent;

(c) a declaration that the claims of the '861 patent are invalid;

(d) a declaration that Teva is entitled to no damages, interest, costs, or other relief from or against Lupin for infringement of the '861 patent pursuant to 35 U.S.C. § 271 (e)(4), or any other provision of law; and

(e) such other and further relief as the Court may deem just and proper.

October 29, 2009

/s/ Karen A. Confoy

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2 AND 40.1 OF LUPIN PHARMACEUTICALS, INC. AND LUPIN, LTD.

Pursuant to Local Civil Rule 11.2 and 40.1, Defendants and Counter-Plaintiffs Lupin Pharmaceuticals, Inc. and Lupin Limited, by their attorneys, hereby certify to the best of their knowledge and belief that the matter in controversy, particularly the patent-in-suit (U.S. Patent No. Re. 39,861), in the above-captioned matter is the subject of the following actions:

1. Duramed Pharmaceuticals, Inc. v. Sandoz, Inc. Watson Pharma, Inc., Watson Laboratories, Inc., and Watson Pharmaceuticals, Inc., Civil Action No. 07-5940 (MLC) (TJB), in the United States District Court for the District of New Jersey.

I certify that the foregoing statements are within my personal knowledge pursuant to Local Civil Rule 7.2.

October 29, 2009

Respectfully submitted,

/s/ Karen A. Confoy

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true copy of the foregoing ANSWER AND COUNTERCLAIM OF LUPIN PHARMACEUTICALS, INC. AND LUPIN, LTD. was electronically filed with the Clerk of Court using CM/ECF on October 29, 2009, which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

The undersigned further certifies that on October 29, 2009, the attached document was served to the following persons by email and U.S. mail, addressed as follows:

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